FLIXONASE™

Fluticasone propionate

Aqueous Nasal Spray

To the Medical and Pharmaceutical Professions.

Presentations

Nasal spray, suspension.

Qualitative and Quantitative Composition:

Fluticasone propionate 0.05% w/w. Each metered dose contains 50 micrograms of Fluticasone propionate. (See List of excipients)

Indications

Fluticasone propionate Aqueous Nasal Spray is indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hay fever, and perennial rhinitis.

Dosage and Administration

For nasal use

Shake gently before use. For practical details on operation and cleaning procedures see the Patient Information Leaflet.

Adults and children over 12 years of age: For the prophylaxis and treatment of seasonal allergic rhinitis and perennial rhinitis:

Two sprays into each nostril once a day, preferably in the morning. In some cases two sprays into each nostril twice daily may be required.

The maximum daily dose should not exceed four sprays into each nostril.

Elderly:

The normal adult dosage is applicable.

Children under 12 years of age: For the prophylaxis and treatment of seasonal allergic rhinitis and perennial rhinitis in children aged 4-11 years:

One spray into each nostril once a day, preferably in the morning. In some cases one spray into each nostril twice daily may be required. The maximum daily dose should not exceed two sprays into each nostril.

The minimum dose should be used at which effective control of symptoms is maintained.

There are no clinical data on the efficacy of FLIXONASE Aqueous Nasal Spray in children under 4 years of age.

For full therapeutic benefit regular usage is essential. The absence of an immediate effect should be explained to the patient as maximum relief may not be obtained until after 3 to 4 days of treatment.

Do not administer Flixonase Aqueous Nasal Spray for more than 3 weeks if no response is achieved.

Contra-indications

Fluticasone propionate Aqueous Nasal Spray is contra-indicated in patients with a hypersensitivity to any of its ingredients.

Precautions and Warnings

Any corticosteroid administered by the nasal route may cause systemic effects, especially when used in high doses and for prolonged periods. Therefore it is important to check patients periodically and to reduce the dose of inhaled corticoid to the minimum dose at which effective control of the disease can be maintained.

It is recommended to monitor the height of children and adolescents receiving prolonged treatment with corticosteroids by the nasal route.

Treatment with doses higher than recommended can cause clinically significant adrenal suppression and therefore the possible need for additional systemic corticosteroids during periods of stress or elective surgery should be taken into account.

Infections of the nasal airways should be appropriately treated.

The full benefit of Fluticasone propionate Aqueous Nasal Spray may not be achieved until treatment has been administered for several days.

Care must be taken while transferring patients from systemic steroid treatment to Fluticasone propionate Aqueous Nasal Spray if there is any reason to suppose that their adrenal function is impaired.

Although Fluticasone propionate Aqueous Nasal Spray will control seasonal allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may in certain instances necessitate appropriate additional therapy.

During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving Fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of Fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side-effects (see Interactions).

Drug Interactions

Under normal circumstances, very low plasma concentrations of Fluticasone propionate are achieved after intranasal dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome P450 3A4 in the gut and liver. Hence, clinically significant drug interactions mediated by Fluticasone propionate are unlikely.

A drug interaction study in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can greatly increase Fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving Fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of Fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects.

Studies have shown that other inhibitors of cytochrome P450 3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to Fluticasone propionate without notable reductions in serum cortisol concentrations. Nevertheless, care is advised when coadministering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole), as there is potential for increased systemic exposure to Fluticasone propionate.

Pregnancy and Lactation

As with other drugs, the use of Fluticasone propionate Aqueous Nasal Spray during pregnancy and lactation requires that the benefits be weighed against the possible risks associated with the product or with any alternative therapy.

Adverse Reactions

Adverse events are listed below by system organ class and frequency.

Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports.

Very common, common and uncommon events were generally determined from clinical trial data.

Rare and very rare events were generally determined from spontaneous data. In assigning adverse event frequencies, the background rates in placebo groups were not taken into account, since these rates were generally comparable to those in the active treatment group.

Immune system disorders:

Very rare: Hypersensitivity reactions, anaphylaxis/anaphylactic reactions, bronchospasm, skin rash, oedema of the face or tongue.

Endocrine disorders

Very rare : Adrenal suppression, retarded growth in children and adolescents and reduced bone density.

Nervous system disorders:

Common: Headache, unpleasant taste, unpleasant smell.

As with other nasal sprays, unpleasant taste and smell and headache have been reported.

Eye disorders:

Very rare: Glaucoma, raised intraocular pressure, cataract.

Respiratory, thoracic and mediastinal disorders:

Very common: Epistaxis.

Common: Nasal dryness, nasal irritation, throat dryness, throat irritation. Candidiasis in the mouth and throat.

Very rare: Nasal septal perforation.

As with other nasal sprays, dryness and irritation of the nose and throat, and epistaxis have been reported. *Nasal septal perforation has also been reported following the use of intranasal corticosteroids.

Both hoarseness and the incidence of candidiasis can be alleviated by gargling with water after using this product. Symptomatic candidiasis can be treated by topical antifungal therapy while continuing treatment with Flixonase nasal spray.

Overdosage

There are no data from patients available on the effects of acute or chronic overdosage with intranasal fluticasone propionate. In healthy volunteers, intranasal administration of 2 mg fluticasone propionate twice daily for seven days had no effect on hypothalamic-pituitary-adrenal (HPA) axis function.

Administration of doses higher than those recommended over a long period of time may lead to temporary suppression of adrenal function, treatment should be continued at a dose sufficient to control symptoms; adrenal function will recover in a few days and can be monitored by measuring plasma cortisol.

Pharmaceutical Information

Storage

Do not store above 30°C.

List of Excipients

Glucose (anhydrous), Microcrystalline cellulose and sodium carboxymethylcellulose, Phenylethyl alcohol, Benzalkonium chloride, Polysorbate 80, dilute hydrochloric acid, purified water.

Instructions for Use

Shake gently before use.

Refer to instructions for Use/Handling at the beginning of the leaflet.

THIS IS MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. • Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. • The doctor and the pharmacist are the experts in medicines, their benefits and risks. • Do not by yourself interrupt the period of treatment prescribed. • Do not repeat the same prescription without consulting your doctor. • Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists.

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*Member of the GlaxoSmithKline group of companies

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